Exhibit 3

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HTWR - Q2 2014 HeartWare International Inc Earnings Call

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PRESENTATION

Operator

Greetings, and welcome to the HeartWare International Second-Quarter Results Conference Call.

(Operator Instructions)

As a reminder, this conference is being recorded. At this time, I would like to turn the floor over to the HeartWare International management team. Thank you. You may begin.

Chris Taylor - *HeartWare International Inc - VP of IR & Corporate Communications*

Thank you, operator, and thank you all for joining us for the HeartWare International conference call and webcast to review the results for the second quarter of 2014.

During the course of this conference call, the Company will make forward-looking statements pursuant to the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995. Including statements regarding our financial performance, commercialization, clinical trials, regulatory status, quality compliance, development pipeline and business trends. These statements are neither promises nor guarantees, but involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements.

A detailed discussion of the risks and uncertainties that affect the Company's business and qualify the forward-looking statements made in this call is contained in HeartWare's filings with the SEC. Particularly under the heading Risk Factors described in the Company's annual report on Form

10-K, and contained within the other filings that the Company makes from time to time with the SEC. Copies of HeartWare's SEC filings and the news release for this earnings call are available online from the SEC, or by clicking on Investor Relations on the HeartWare website.

Any forward-looking statements are based on judgment, assumptions, estimates and other factors that are subject to change. And therefore, these statements speak only as of the date they are given. The Company does not undertake an obligation to update any forward-looking statements.

Participating on the call today are HeartWare's CEO and President, Doug Godshall, and Chief Financial Officer, Peter McAree. Each will provide a commentary on the Company's second-quarter financial results, as well as a corporate update. Those prepared comments will be followed by a question and answer session.

In the interest of time and with the goal of allowing as many of you to propose questions as possible, we respectfully ask you to limit yourself to one question and one concise follow-up, and then please feel free to return to the queue. Thanks very much. And now I'd like to turn the call over to Doug Godshall. Good morning, Doug.

Doug Godshall - *HeartWare International Inc - President & CEO*

Thanks, Chris.

The first six months of 2014 have been remarkable in so many ways for HeartWare. We've been blessed by extraordinary support of our clinical partners, but we have also had a series of events this year which let us to embark upon an upgrade of our quality system.

We've always focused on our customers and their patients, and this has helped inspire our innovation and defines our long-term direction. At the same time, field actions and a warning letter made quite apparent that we needed to do a bit of structural reinforcement to ensure that our performance was up to the expectations of our customers.

On the subject of the warning letter, from the moment it arrived, it became our highest priority. We immediately began to shift energy, attention, and resources to address the observations. In the weeks since, we have made meaningful progress in reorganizing our leadership team, and commencing the upgrades of our processes. We have completed program assessments to understand how this new more rigorous approach will affect our core pipeline projects, and we have infused our team with seasoned external experts to help supplement our skills and expedite the mitigation process.

This week, we will be submitting our first report to the FDA, which we will do every other month. The amount of work we have ahead of us is considerable, but I am confident in our ability to improve our systems and capabilities to achieve a higher level of performance. Trying to speculate as to how long it will take before our capabilities and performance warrant removal of the warning letter is not really prudent, but we expect that the time required will be measured more in fiscal quarters that in weeks or months.

I realize this is a non-standard opening to our call. And that I have yet to even mention what an encouraging quarter we had in the market, or how well our team is executing in the field. I wanted to begin our call with the backdrop of our cleanup effort, so it is clear to everyone where our focus is at this time. We obviously did not do as good a job as we should have in ensuring that our quality system kept pace with the rapid growth and the increasing complexity of our business.

But once we're on the other side of this process, we believe HeartWare will be a substantially stronger, more efficient Company than we are today. I'll provide more color on the business after Peter discusses the financials. Peter?

Peter McAree - *HeartWare International Inc - CFO*

Thank you, Doug.

We're pleased to report another solid performance for the second-quarter of 2014. Highlighted by strong revenue growth, continued gross margin improvement, an improved bottom line and positive operating cash flows.

Our team generated sales of 674 HVAD systems during the quarter, compared to 523 systems during the second-quarter of 2013. The unit sales were split roughly evenly between the US and international markets, with 338 HVADs sold in the US, and 336 HVADs sold internationally during the second-quarter. This represents another new record high for unit sales in a quarter, exceeding our Q1 mark of 665 units.

We posted worldwide revenue of $70.1 million in the second-quarter, a 38% increase from $50.8 million in the second-quarter of 2013, which includes 3 percentage points from favorable currency changes. US revenue during the second-quarter was $36.9 million, which represents a 47% increase from $25.1 million in the second-quarter of 2013.

There were 36 supplemental destination therapy trial units sold during the second-quarter, a slight increase from Q1. And, we added four new sites in the US during the second-quarter.

International revenue during the second-quarter was $33.2 million, a 29% increase from $25.7 million in the second-quarter of 2013. Providing a little color, compared to the second-quarter of 2013, revenues from international markets, excluding Germany, grew at 31%, which modestly outpaced the growth in Germany at 27%. During the quarter, we added 12 new international customers.

We've realized an improvement in gross margin percentage to 67.3% in the second-quarter, compared to 65.5% in the first-quarter of 2014, and 62.9% in the second-quarter of 2013. The improvement compared to the second-quarter of 2013 of 4.4 percentage points is primarily the result of manufacturing efficiencies tied to higher volumes. Whereas, the sequential improvement compared to Q1 was primarily the result of an increase in average selling price, along with minor variable cost improvements.

This morning, we announced a plan to replace certain older batteries in the field as an expansion of the field correction we implemented in April. As a result of this voluntary recall, we recognized a $1.7 million charge in the second quarter, which is reflected in cost of revenue.

Operating expenses in the second-quarter of 2014 decreased to $34.2 million, compared to $60 million in the first-quarter of 2014, and $41.4 million in the second-quarter of 2013. The total operating expenses declined sequentially, due to a $13.7 million reduction in the estimated fair value of the contingent consideration related to the CircuLite acquisition. This non-recurring benefit was also the primary factor resulting in positive GAAP net income in the second-quarter of 2014.

The basis for the $13.7 million reduction of fair value of our contingent obligation is the increased probability of not meeting the first milestone payment, given the increased likelihood of a clinical study prior to the relaunch of the SYNERGY system in Europe.

As a reminder, we carry liability for the fair value of the contingent milestone payments that may be payable over a 10-year period in connection with our acquisition. This calculation is adjusted each quarter for accretion related to the passage of time, and for changes in the probability of achieving each potential milestone as additional information becomes available.

The contingent liability was valued at approximately $56 million at June 30th, compared to $70 million at March 31st, and $67 million at the end of 2013. The maximum amount of aggregate milestone and success based payments could be up to $320 million in total.

As with recent quarters, we have provided a non-GAAP reconciliation to supplement our GAAP financial reporting by excluding items such as fair value adjustments associated with the contingent milestone payments I previously mentioned. The purpose of these reconciliations is to enhance comparability of the current financial statements to prior periods.

SG&A expenses decreased by approximately $3.3 million to $20.9 million in the second-quarter, from $24.2 million in the first-quarter of 2014. This sequential decrease was primarily a result of CircuLite restructuring costs incurred in the first-quarter of approximately $3 million, principally related to the closure of the former New Jersey headquarters. We expect our selling, general, and administrative expenses to increase periodically, as we

continue to expand our commercial sales and distribution capabilities globally, as well as enhance our administrative infrastructure to support our ongoing growth.

Research and development expense decreased by approximately $5.7 million to $26.9 million in the second-quarter from $32.6 million in the first-quarter of 2014. The Q2 sequential decrease was primarily the result of reduced consumable spending and lower project costs. We expect to see R&D spending go up in Q3 and Q4, more closely in line with Q1 spending levels.

We expect that R&D expenses will continue to represent a significant portion of our operating expenses for the foreseeable future, as we continue to enhance our pipeline, and perform ongoing clinical trials.

As Doug mentioned, addressing the improvement needs highlighted by the warning letter will undoubtedly impact certain areas of spending. Although, it's too early for us to quantify the impact of these prospective investment needs.

Moving to the bottom line, net income on a GAAP basis for the second-quarter of 2014 was positive $8.4 million or $0.48 per diluted share. As compared to a net loss of $12.9 million or $0.79 per basic and diluted share in the second-quarter of 2013.

There were approximately 17 million shares outstanding at the end of the second-quarter. And weighted average shares outstanding, for the purposes of computing basic and diluted earnings-per-share, were 17 million and 17.3 million shares respectively for the second-quarter.

Our non-GAAP net loss for the second-quarter of 2014, which is perhaps a more informative comparison, was $4.9 million or $0.29 per basic and diluted share. Compared to a net loss of $12.9 million or $0.79 per basic and diluted share in the second-quarter of 2013. Please refer to the supplemental non-GAAP tables within our earnings release to fully understand these non-GAAP measures.

As of June 30th, we had approximately $184 million in cash and investments, an increase from $181 million on hand at the end of last quarter. During the second-quarter, we generated $5 million of positive operating cash flows, primarily as a result of AR collections, boosted by strong preceding quarter sales.

We had investing cash uses in Q2 of approximately $2 million for property, plants, and equipment, and IP investments... and had nominal proceeds from option exercises. We are not yet in a position that we can expect positive operating cash flows on a routine basis, and we generally expect to utilize cash for operations in coming quarters as we continue to invest in growing the business.

In summary, financial results for the second-quarter were quite solid. And while we always caution about variability on a quarter-to-quarter basis, it feels like we're in a good position as we move into the back half of the year.

Thanks for your time this morning, and I welcome your questions when we move to the Q&A, and back to Doug.

Doug Godshall - *HeartWare International Inc - President & CEO*

Thanks, Peter.

Clearly, we are benefiting from strong global support for the HVAD, and we are working hard to continue to find ways to further enhance its performance in the clinic. One such effort is the second arm of our ENDURANCE destination therapy study. And while enrollment was a bit slower than anticipated in the second-quarter, it began picking up in June and July, and we currently find ourselves with 150 patients enrolled, representing nearly one-third of the study.

Our principal investigators have engaged aggressively, and they are working closely with us to help accelerate and complete this important arm of the trial. At this juncture, we believe we are on track to complete enrollment in the first- or second-quarter of next year, depending on whether the recent ramp is sustained.

Looking at the commercial market in the US, we are certainly encouraged by the results generated in the second-quarter, especially following such a positive first-quarter. The addition of four new US centers tracks with our expectations that we will add approximately 3 to 5 new customers in the US each quarter.

Our team remains focused on being responsive to each of our existing customers, and ensuring that they have the support and training needed to provide optimal patient outcomes. We are confident that we will continue to add new sites steadily over time, as long as existing customers continue to share positive reports of their experiences with HVAD.

22 US sites conducted thoracotomies in the quarter. And the number of thoracotomies performed increased for the 5th straight quarter, both in the US and internationally. The numbers have basically quadrupled in the past year.

The feedback we hear from the market continues to suggest that there is a positive bias towards thoracotomy in sites that are using the technique and those who plan to use it in the future. This potential, along with other positive HVAD attributes, seems to be helping drive continued adoption at new and existing sites.

While on the subject of thoracotomy, we just recently confirmed our direction with the FDA on this topic. Currently, our label describes HVAD implantation via median sternotomy, rather through the less invasive thoracotomy technique.

We received full approval to commence an IDE study in the second-quarter, but were encouraged by the agency to consider a less burdensome strategy for approval using existing data to support the approval. Based on their feedback, we proposed a plan to utilize existing INTERMACS data to accelerate a label change.

From a business perspective, we were always torn about using retrospective data, as it might give us a faster label change, but we would have no ability to structure a prospective study nor share best practices with the clinical community.

In a conversation with the agency last week it became evident that the IDE trial is the one that they were more comfortable with, despite their prior encouragement to consider a different path. The agency suggests that we consider using a performance goal versus an active control arm, which does reduce the sample size. So we are drafting an amended protocol which should lead to approximately 120 patients in the study.

Now that the strategy is settled, we are beginning to select sites, create a training plan, and spooling up all the activities required to kick off a trial, which should commence in early fourth-quarter. We are delighted to finally have a firm path forward, and we now have the ability to generate the interest and momentum that a trial often produces, and demonstrate a clear prospective understanding of the benefits of this less invasive surgical technique.

We continue to be encouraged by the expansion of that therapy in international markets, and enthusiasm for HVAD remains quite high. We are proud of our team's work, as we added 12 new implanting sites in the second-quarter. Impressively matching what they achieved in the first-quarter, and well ahead of our expectations.

Our team facilitated initial HVAD implants in three new countries during the second-quarter. Expanding our global footprint to 40 countries in which a patient has received an HVAD system as a treatment for their advanced heart failure. Today, we are pleased to report that more than 6,000 advanced heart failure patients worldwide have received an HVAD. The longest of whom has been on support for more than seven years.

In order to build on this momentum, we need to improve our performance so we can focus on growing our business and helping more patients. An important step in this direction is to make sure we have the right people in the right positions to succeed.

As I mentioned in my opening comments, we have undergone a few organizational changes recently, which we feel will be beneficial both in near and long-term.

First, we are quite pleased to announce today that we have named Dr. Katrin Leadley as Chief Medical Officer for HeartWare. Catherine brings to HeartWare extensive strategic leadership, with more than 15 years of clinical and regulatory experience. Working at both small and large device firms, including Boston Scientific, and most recently JenaValve, where he she spent the last three years as Chief Medical Officer leading the company's clinical, regulatory, and scientific, and medical activities.

She has a wealth of clinical program management experience, has built relationships with many of our key customers, and works collaboratively with many of the same regulators we work with today. Catherine will be able to partner with Dr. Dan Burkhoff, who joined us via the CircuLite acquisition, and is recognized as a global thought leader in the heart failure and VAD communities.

David Hathaway, who assembled a very strong team here at HeartWare has decided to retire, and we thank him for his leadership and contributions of the past six years.

We also recently promoted Mark Strong to Senior Vice President over research and development and quality affairs. Mark joined us last year as our Vice President of R&D, after tenure of over 20 years in quality and R&D at Guidant. For those of you who have heard me speak about Mark, you know how impressed we have been with his intensity, rigor, and execution excellence. These attributes have resulted in a transformation in the integrity of our R&D performance over the past nine months. His background and ability to make an immediate impact made him the ideal choice to take on this added responsibility.

Enthusiasm for the MVAD remains incredibly high, as we witnessed in an international investigators call held earlier this week. The performance of the system continues to impress, and we are eager to enter the clinic to demonstrate all the assumed advantages of the system prove out in patients.

That said, we spoke last month of the need to step back and assess what if any impact of the warning letter would have on the MVAD program. It was imperative that we confirm that the sorts of issues that concern the agency were not present in our MVAD program, since the last thing we can afford to do is to make the same mistakes twice.

Unfortunately, we did discover that we have some additional work to do and it will delay the submission to commence our CE trial. It now appears that this submission will occur towards the end of this year or early next, versus this Summer, as we had been planning.

We also have decided to focus all of our efforts on our two approval trials, CE Mark and IDE, versus trying to get into Canada earlier via special access as had been our initial thought. We hope to include Canadian sites in our FDA trial, or conduct a standalone smaller Canadian study. We plan to submit in the US soon after we submit internationally, assuming we receive positive feedback from the FDA on our study design.

While the Company's clear number one objective is to address the warning letter as expeditiously as possible, the MVAD is a very close number two in terms of organizational attention and commitment. Clearly, no one is excited about moving the MVAD start out a few months. But it would be intolerable to leave regulatory risks in the program, particularly in light of our current status.

On the subject of quality activities, you likely recall that in April of this year we implemented a device correction that provided information to assist patients and clinicians on how to best manage the power system for the HVAD. Historically, we've experienced a higher battery related complaint rate in Germany than in other territories. And following correspondence with German regulators regarding the field action, we decided to expand our field safety correction to include a voluntary recall of certain older batteries, and replace them with new batteries which have gone through additional screening tests that were implemented last year.

Once we came to the decision to conduct this replacement in Germany, we determined that we should adopt the same policy in all countries. Existing HVAD patients with batteries built basically a year or longer ago, will simply replace them with newer batteries when they visit their physicians during their next routine visit. We anticipate it will take a few months to complete the replacement of those older batteries.

As we progress, and the thousands of implants and ever lengthening patient support times, we will continue to learn more about how to make our system better and how to manage it better. We remain committed to make improvements to enhance product performance, and communicating information that may be helpful to our customers and their patients to ensure best possible outcomes.

Just to touch briefly on a couple other ongoing clinical efforts to expand access to HVAD in terms of new geographies and new indications. In our Japan bridge-to-transplant study, we are pleased to report that all five of our centers have received IRB approval, which should enable them all to have at least one implant in the trial.

Thus far, four of the six patients have been implanted at three of the centers. With the final sites clearing IRB recently, the last two cases have been scheduled for August. If everything goes according to plan, we will be on schedule for the last patient to complete follow-up in February, so we should be in a position to file for approval in the middle of next year.

Given the growth of the VAD market in Japan, we are quite pleased that the leading sites in that important country will have an opportunity to gain experience with HVAD and move us forward in the regulatory process.

With a dozen or so BiVADs performed each quarter around the world, it is clear many more would be used were reimbursement in place. We have been in dialogue with our notified body about our international trial design, and we are hopeful that we can commence a BiVAD clinical trial later this year. With the aim of generating the data that secures approval for right heart support, and creates a much more viable reimbursement path for surgeons wishing to utilize an HVAD on both the left and right ventricles of some of their sickest heart failure patients.

And finally, on the topic of the SYNERGY partial assist platform, which we added to our pipeline through the acquisition of CircuLite in December. Last quarter, we discussed plans regarding enhancements that we are making to improve the stability of the inflow cannula, and modifications to the pump itself to reduce sheer stress and thrombogenicity of the system.

Our initial pump tests have produced very encouraging results, and we are commencing tests this week that will enable us to identify the final impeller geometry. If things continue to progress as well as they have thus far, we should see a similar kind of sheer and efficiency improvement in CircuLite as we witnessed in our revised MVAD impeller.

We expect that sometime later this year we'll be able to have a conversation with the European regulators about how to return to market most efficiently. Given test requirements and regulatory timelines, we expect to return to clinic next year with some form of trial to generate clean data with a meaningfully improved pump and cannulas design that would then lead to a relaunch of the product.

It continues to amaze me how enthusiastic clinicians are about the potential of this system for a broad spectrum of patient populations. We look forward to updating you regarding our progress regarding the SYNERGY as we move forward to re-initiating a clinical effort for both surgical and endovascular systems.

Thank you very much for your time, attention, and support. We are fortunate to have such tremendous support from our customers as well as shareholders, as we build a meaningfully stronger organization that will be capable of capitalizing on the significant opportunity that is present in our pipeline.

That concludes our prepared commentary. So, operator, at this time, you can now open the call to questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Chris Pasquale, JPMorgan.

Chris Pasquale - *JPMorgan Securities Inc. - Analyst*

Thanks. Good morning.

Doug Godshall - *HeartWare International Inc - President & CEO*

Hello, Chris.

Chris Pasquale - *JPMorgan Securities Inc. - Analyst*

Doug, I just want to circle back on MVAD for a minute. So what aspects of the warning letter impact MVAD specifically, and can you be a little bit more granular about what the revised timeline now looks like in both Europe and the US? When do you expect to file the study protocols, and what would that mean for the likely start of implants?

Doug Godshall - *HeartWare International Inc - President & CEO*

Thanks, Chris.

So as you walk through the four main categories of the warning letter validation, CAPAs, et cetera, one of the areas is the software validation work that you have to do on equipment that you use -- not on the system itself, but on the equipment they used to build the system, the product. And that is a fairly pervasive request by the agency, and we want to make sure that everything that we used to test and validate MVAD is up to standard.

And we also have done a full review of all the other documentation and testing that we've done. And we just want to make sure that there is no question about the integrity of the test reports that we have in-house, and so we're actively buttoning all that up as well. So, incremental to the warning letter, we want to make sure that we are bulletproof when we submit and they don't suggest that there was a looseness, whether it's in test reports or validation work.

In terms of the timing, our expectation is later in the fourth-quarter or early first depending on when the last documents are produced that we would be submitting to competent authorities in Europe. And in between there, we'll be reviewing our protocol with the agency to confirm that we would be able to start in the US contemporaneous with Europe, rather than waiting for European data which is our current plan.

So we would likely have a gap of a month or so before we submit in the US, but not several quarters as we have traditionally done. That would suggest that our first implant best case is first-quarter next year internationally, if everything is submitted and reviewed timely. And it would be sometime soon thereafter hopefully in the US.

Chris Pasquale - *JPMorgan Securities Inc. - Analyst*

And what's the thinking behind not doing the first-in-man series in Canada just to gain some human experience while you wait it out here on the quality side?

Doug Godshall - *HeartWare International Inc - President & CEO*

So a couple things. First, as we described last month, we were running into challenges with Canada just figuring out what patient population you actually could justify using the MVAD in that no other pump could work for. And so as the arguments started progressing between the physician

and the regulators, it started to get very uncomfortable. Because you started describing biventricular failure patients with very small chests, et cetera, et cetera, and those are the kind of patients that aren't going to do well.

And so the fact that between HVAD and HeartMate II, you can treat just about everybody. The whole purpose of special access is get it to provide Canadian citizens with access to a device where there is no other device available that can treat them. And so as other companies have recently witnessed as more technology is available, it's harder to carve out a specific patient population that is otherwise untreated.

So as we saw the diminishing returns of that argument, and then simultaneously received a special access from the agency, we realized that having a separate somewhat less tested system go into Canada was perhaps not in anyone's best interest. Although, obviously, we would not have gone in if we didn't have high confidence in the safety of the device.

But just managing multiple revisions of the controller and pump and everything just seemed like it was also fraught with risk that was not worth taking. And so the combination of not knowing if we could even navigate the regulators and embedding risk, we felt we would leave what was always an opportunistic strategy in Canada and go back to a more traditional trial approach.

Chris Pasquale - *JPMorgan Securities Inc. - Analyst*

Okay. Thanks, Doug, and congrats on the good quarter.

Doug Godshall - *HeartWare International Inc - President & CEO*

Thanks.

Operator

Matthew Taylor, Barclays.

Matthew Taylor - *Barclays Capital - Analyst*

I just had a follow-up on MVAD. So you mentioned the best case is first quarter of 2015. Can you just talk about any risks to that timeline in terms of steps that may cause you to be delayed?

And do you think a worst case is Q2 2015 if there's some administrative delay here? Or do you think it could be meaningfully delayed from that?

Doug Godshall - *HeartWare International Inc - President & CEO*

So, I'm reluctant to describe worst cases because we've -- I think we've demonstrated we have the ability to delay MVAD longer than I had hoped. So I don't want to predict what could happen, because you can always end up with some unanticipated failure that you discover in some routine testing that causes you to take a pause. We certainly don't expect that. So what could delay it?

If we do discover something that requires us to change layout of a board or a component in the system or something like that, in theory, that could push us out further. If there's a regulatory delay and it takes multiple months to review the submissions, then that would push us into the second quarter. It would require a fairly efficient regulatory review to get into the first-quarter, which is why I'm describing it as best case.

That said, even though we're doing this last cleanup a bit on MVAD, as our internal group looks at integrity of the MVAD documentation relative to the HVAD documentation that invited the FDA response, it's materially stronger than the work that we did on HVAD years ago that we're cleaning up now.

If you drew a line from HVAD to where we'll be a year from now, post a warning letter response, MVAD is maybe three-quarters of the way there in terms of integrity. And a lot closer to where we're ultimately going to be, therefore, the amount of activity we need to do to tighten up the MVAD program is much less which is why we think it's only a few months to get there.

Matthew Taylor - *Barclays Capital - Analyst*

Thanks. And maybe just switching gears, you did have a pretty nice quarter here with new highs on pumps in the US. Can you just talk about some of the US dynamics?

It looks like you're continuing to gain a lot of share in BTT, but the DT enrollment has been a little bit slower. I guess, how much room do you have left in terms of adding centers and share within centers in BTT, and then what's going to accelerate that DT enrollment?

Doug Godshall - *HeartWare International Inc - President & CEO*

Yes. We were certainly relieved that June started picking up, and then July was much more in line with what we had been expecting. So there was a bit of a April, May softness in DT that was a little befuddling. But, we also, as we modified our -- had modifications to our clinical department, which currently everybody is reporting to me until Katrin starts in September.

We started really ramping up our communications with our sites, holding more investigator calls, collaborating far more closely with our PI's, as well as tasking two of our more senior clinical specialist experts to specifically work on each site to understand if there are any barriers to enrollment. What are the objections to the trial, or any concerns or any needs to enhance training on blood pressure management, and the like. To ensure that we're maintaining a high level of screening, which would then of course translate into enrollment.

So I think a combination of activities and renewed focus on our end is perhaps somewhat responsible. And there's probably also just one of those usual odd lumpiness' that happened in April and May that adversely affected this. So we -- I think we're on the right path now.

There's renewed energy in the program. And I don't think that July was an anomaly, and hope that it's more of the go forward trend.

In terms of our -- the market dynamics. Just like last quarter, when we weren't quite sure exactly how the overall market did since we only have visibility to our portion of it, we remain long-term quite bullish as always. We're flattered by the strength of the reception we're getting in our sites. We also see meaningful upside in bridge volume at a lot of these centers.

As we continue to analyze the sites, we are encouraged that we are seeing growth both at quote-unquote old sites, so the old IDE centers, or the ones we've had for more than a year did grow. New sites obviously contributed very nicely. And there remain several key large centers that are either not using the HVAD at all or hardly using it at all that we think could have a measurable impact on our volume into the future.

So we don't think we're anywhere near tapped into the full potential of our product for bridge. And hopefully, continue to see uplift in DT implant volume.

Matthew Taylor - *Barclays Capital - Analyst*

Okay, thanks.

Operator

Jason Mills, Canaccord Genuity.

Jason Mills - *Canaccord Genuity - Analyst*

Thanks. Hello, Doug. Good morning, thanks for taking the question. Can you hear me okay?

Doug Godshall - *HeartWare International Inc - President & CEO*

Absolutely. Hello, Jason.

Jason Mills - *Canaccord Genuity - Analyst*

Good. Let's circle back to MVAD real quick. Following on some of the earlier questions, walk us back through over the last say 18 months when we started thinking we could get MVAD first-in-man anytime now. And then, we've obviously had some delays, and initially the changes were to the pump, to the system.

The recent delays seem to be more validation testing. I'm just curious if you could give us more granularity to the last time changes were made -- any changes were made to the actual pump or the system, the electronics, the things the patient would interface with day to day? And if not for the warning letter, would you guess best guess think we would have been in the clinic by now?

Doug Godshall - *HeartWare International Inc - President & CEO*

Let's see how -- yes. So last July, we had the unpleasant cannula fracture or ceramic tube fracture phenomenon. September, Mark Strong started. By October, November, we realized that we were going to be able to stick with ceramic, and we found a means of assembling the system that took a lot of stress out of the ceramic and enabled it to maintain its integrity.

And so we were able to keep the same interface between impeller and tube and not switch to a titanium tube that we had thought we were going to have to switch to. So that was a huge win on the pump side, and now it's a piece of cake on the pump side. It's really tight.

And we also used that time to integrate a reduced sheer stress impeller into the system. That did require us to do some incremental testing, animal testing, just to confirm that we weren't introducing something clinically or pre-clinically that our fluid dynamics model would have missed. And again, that has been pristine.

So on the pump side, we're in very good shape. Although, we obviously did have to make sure that all the documentation is in strong condition relative to the FDA expectations, which we thought we were complying with and in retrospect we needed a little buttoning up on.

The other, Mark's strong impact taking a guy who's spent 23, 24 years doing electronics, he saw a lot of stuff on the electronic side that we had an opportunity to improve on. Closing out test reports and the like, and so there was a lot of issues that had been justified or rationalized that he has systematically for the last nine months been closing out.

And so we are really tight now in terms of open issues that could have resulted in challenges from regulators. Because they might have said, well why didn't you just repeat the test, or what have you, rather than justify the test. So Mark has really been buttoning up our approach on the electronic side quite commendably.

And so, that kind of activity combined with the recognition that in the warning letter there are enough points in there that we may have been compliant with our former design controls but we needed to upgrade our design controls procedures. So while you're at it, you'd better make sure MVAD is consistent with what you believe you need to do on the quality system side.

So absent the warning letter, would we be in the clinic right now? We'd be a little bit closer. And I don't know if it would be this month, or next month, or October, or whatever. But it would be probably a little bit sooner.

And yet, if an inspector comes back in here and says, well, that's really nice that you fixed everything on HVAD. But you're a complete knucklehead because you made the same mistakes on MVAD after I gave you a warning letter. So now you're in big trouble.

And so while we're going through this grow up process as a Company, we got to do it the right way. And there's an obviousness as we did our deep dive diagnostic on the MVAD program, what steps we needed to take to put ourselves in a strong position. And will probably result in a faster regulatory review, because we'll have a higher integrity to our documentation.

Jason Mills - *Canaccord Genuity - Analyst*

Thanks for that, Doug. That was helpful. Moving to the market dynamics, again, I understand that you only have access to your data at this point.

But wondering from your data, you said that thoracotomy increased this quarter. I think you said both in the United States and outside of the United States. I'm wondering if you could put a percentage number to that, and just generally speaking how many HVADs were implanted via that implant technique? And in Europe specifically, best guess in terms of your share position at this point, excluding Japan.

Doug Godshall - *HeartWare International Inc - President & CEO*

So thoracotomy in the US is about the same range that it's been. So our implant volume has picked up, but we're still in the circa 16%, 17% implants via thoracotomy as we were last quarter. Europe is interesting, because it seems to have picked up. It's about a third, I think 30%, 33% of our implants were thoracotomy last quarter, which is intriguing.

And our sales team in Europe last year really started commenting about how it was fun for them to have thoracotomy. A, because they're actually allowed to talk about it, unlike our US guys. But, B, it gave them a new product to sell. If you think about the timing and that HVAD got approved in 2009, so they've been at it quite successfully thankfully for several years.

And so to be able to really promote a new way of thinking about the system gave them a reason to talk to some sites that maybe they had run out of things to talk about. So, I'm cautiously optimistic that the same thing might happen in the US when we can switch over to openly discussing thoracotomy, and generating interest and enthusiasm at the trial sites first.

Jason Mills - *Canaccord Genuity - Analyst*

Super. Thanks, Doug. I'll get back in queue.

Doug Godshall - *HeartWare International Inc - President & CEO*

Yes.

Operator

Brooks West, Piper Jaffray.

Brooks West - *Piper Jaffray - Analyst*

Hello. Thanks for taking the question. Doug, I'm just -- I'm looking at all the various trial timelines.

Could we actually see the SYNERGY trial start before we saw MVAD? Would you -- if the timing worked out, would you prioritize that way? And then can you just remind us what the trial program looked like before the product was pulled, and give us an idea of what it might look like going forward?

Doug Godshall - *HeartWare International Inc - President & CEO*

Sure. And sorry I'm not going to be able to see you next week, Brooks.

The -- I would -- boy would I be disappointed if SYNERGY caught up with MVAD. On the other hand, if you put a gun to my head and I had to pick MVAD or SYNERGY, I don't know which I would pick right now. Because the -- whenever we go out and talk about SYNERGY, the room just floods with cardiologists. It's the strangest thing.

It was what we suspected when we bought the company that the cardiologists would be more comfortable with a device that goes under the skin, instead of one that goes under the chest. But it's stunning how enthusiastic they are for a system that has arguably mediocre data, because of all the thrombus and fractures and everything they had. They very comfortably looked past that, and it just seems to intellectually resonate, intellectually and emotionally resonate, with the cardiologists in particular.

I don't think I'm going to have to make that choice. No one is going to put a gun to my head, I think we're going to get to do both thankfully. And I think MVAD is more complete, and so close to being done it's just buttoning it up and finishing the -- SYNERGY on the other hand, we are making modifications to the impeller geometry.

We are really feeling very good about the integrity of the cannula, that had fracture issues before. So we feel like we're going to have a very substantial performance upgrade once we get there. But we're at redesign mode that then has to get validated, that then has to flip into the clinic.

So we're at least a year from submitting for a start of the trial I would project just as if I try to think about the steps we would have to go through to get ourselves in a submission position. So that would suggest whatever -- six, seven months lag from MVAD if all goes well. And maybe even a little bit longer than that, so it will be a back half of 2015 submission for SYNERGY.

And then in terms of what the -- they had a CE mark, and we believe will have to generate clinical data for two reasons. One is, we're making so many changes to the system, even if we still had the CE Mark it wouldn't make -- the product is going to be different enough that we believe now we would have to redo some clinical activity. And, perhaps as importantly, even if we could just immediately relaunch the product, you really want to create a clean data set with which to commercialize it versus the legacy data set that the Company had.

So there are very intriguing elements to their data set. Like once they got through the first few months, the patient survival was fantastic. So their initial survival was not much better than regular VADs, but their long-term survival was really good. Their stroke rates were incredibly low, their thrombus rate was intolerable which is why we're making the impeller designs.

In the US, there was a feasibility trial considered for the class III patient, which means it would be randomized against the standard medical therapy -- or optimal medical therapy. What we're expecting to do is commence our clinical activity with that same class III patient population.

What we will then contemplate very quickly is whether or not or how we would evaluate the technology in patients with Preserved Ejection Fraction. Because that's one of the areas that gets the clinical community incredibly excited that Dan Burkhoff has continued to research, and is getting increasingly optimistic about the potential for that platform.

Brooks West - *Piper Jaffray - Analyst*

Great. I'll leave it at that, Doug. Thanks for that update.

Doug Godshall - *HeartWare International Inc - President & CEO*

Thanks.

Operator

Jayson Bedford, Raymond James.

Jayson Bedford - *Raymond James & Associates - Analyst*

Good morning, and thanks for taking the question.

Doug Godshall - *HeartWare International Inc - President & CEO*

Thanks, Jason.

Jayson Bedford - *Raymond James & Associates - Analyst*

Doug, you mentioned the potential for meaningful upside in bridge volume. And I'm just wondering where do you get this optimism?

Is it related more to deeper penetration into existing accounts? Or is it new sites coming on? And then how quickly do think that bridge market is growing?

Doug Godshall - *HeartWare International Inc - President & CEO*

That's a good question. I'm looking at Peter right now.

I would say both in terms of new or existing. So some of our sites that we -- that I thought we were fully penetrated in, we've continued to see growth in. And it's a small handful that I would argue we were fully penetrated in.

Peter McAree - *HeartWare International Inc - CFO*

Still, without giving out percentages, when we look at the larger implanting sites overall in BTT, there's still plenty of room upside for us to access accounts that we're not currently in. And then to add to what Doug said, we actually just took a fairly recent look at just implanting volumes overall. And they remain -- our implanting penetration rates continue to perform, and increase, well both among existing sites as well as new sites. And it's hard to predict the trajectory of the newer sites, but the indications are very strong that the implanting rates are increasing nicely even at the lesser sized newer sites.

Doug Godshall - *HeartWare International Inc - President & CEO*

And then, in terms of market growth, it is evident to us that it continues to grow, BTT. But I've not thought about a number. So I'm not going to make up a number on the phone, but we'll go back and do a little noodling on it. But it -- and it is a little hard having a picture on the market... it'll be more helpful obviously in a week when we see both reports.

Jayson Bedford - *Raymond James & Associates - Analyst*

Fair enough. Just a quick follow-up, the DT study, I think you mentioned 150 patients enrolled currently. What was it at the end of 2Q? Thanks.

Doug Godshall - *HeartWare International Inc - President & CEO*

So I'm trying to remember -- so we reported as of the earnings call last time how many had enrolled, if you remember what that number was? Basically, we did so far this year -- I'm just looking at a number Chris has.

Just to get the number for my last report. What's our last report? And then I'll update later. I'll get that before the end of the call.

Jayson Bedford - *Raymond James & Associates - Analyst*

All right. Thanks.

Operator

Larry Biegelsen, Wells Fargo.

Larry Biegelsen - *Wells Fargo Securities, LLC - Analyst*

Hey, good morning guys. Thanks for taking the question. Just circling back, one on MVAD, one on the OUS market.

Doug, in the past, I think you said you thought it was prudent to do a first-in-man series with MVAD before starting the CE Mark trial and the US trial. It doesn't sound like, unless I've just misheard, that you're planning to do that any more. So can you talk about why, and if that has changed? And I just had one follow-up on the OUS market.

Doug Godshall - *HeartWare International Inc - President & CEO*

Sure. Yes, it was -- we liked the idea, obviously, if we can do a few patients before we hit a clinical trial. But we also were always -- we always tried to make sure folks understood that if special access didn't work out or the timing of a CE Mark trial started to coincide with special access, then we would just go right to CE trial. Because we were confident enough in the device that we didn't think it was necessary, but it was, we thought, it was easy and opportunistic to go to Canada under special access first.

As it turns out, it was hard and the door closed, at least for this type of VAD for special access. Maybe a device like CircuLite is different enough that you would say this can treat a patient population that is otherwise untreatable. And then Canada might say, oh I believe you on CircuLite because you're right there's nothing for preserved ejection fractions.

So you can come in on CircuLite, whereas you can't come in on MVAD. I could see that the door still being opened for something like that, but my impression is that Edwards ran into a similar situation with their valve. Where they had gone in under special access multiple times before, and

when you go -- they went in again with their more recent design. And Canada said no, because you can't convince us that there's a patient that is otherwise untreatable with the existing devices.

So, once that opportunity closed and we thought, well, do we fight harder? We also simultaneously got the letter from the FDA, and the prospect of trying to manage a Canadian special access only controller version, while also producing controllers for US and Europe, it just seemed fraught with peril. And we were not confident that we'd be able to convince Canada to come along.

So we have plenty of work to do, both in terms of completing the MVAD activities, and obviously flowing resources towards warning letters, mitigation. So we dropped the early opportunistic special access, and we didn't try to find a country, other than Canada, that we could go to. We just decided to make sure we were highly confident in the system when we go to Europe and the US. And then you had a question --

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Larry Biegelsen - *Wells Fargo Securities, LLC - Analyst*

You know what, I'm going to ask about just ENDURANCE and the plan for the top line results. Just an update on that. Or have you guys decided if you'll top line results, or what's the communication plan on ENDURANCE? And I'll drop. Thanks.

Doug Godshall - *HeartWare International Inc - President & CEO*

Sure. And so to answer Jayson's question first, on May 1st, we said we had just over 80 patients enrolled in DT. So May 1st to I guess teetering on August 1st, it went from 80 to 150. The top line results, we continued to dialogue internally, as you know, Larry, because I think we chatted with it last time I was with you about the challenge of top line versus full clinical data download.

We will be calculating our primary endpoint later this year. And if we come out and say, we have met our primary endpoint, which is what we had predicted last time we spoke on this topic last year, and if you say you hit your primary input but you say nothing else about topics of significant interest like thrombus and stroke, have you really provided the full story is part of the challenge. And if you start providing the full story, then you've stolen the opportunity from the principal investigators to present the data.

Which they have made it quite clear to us, they do not want to see us presenting the trial. They want to present the trial. And so it's the -- we continue to debate how to best manage the process, both in terms of honoring our obligation to the trial and the physicians, as well as recognizing that keen interest amongst the street to have the data.

Recognizing, however, that as we've said all along, the second cohort of the patients we are enrolling this to demonstrate that could we can reduce neurologic events and that we plan to submit both arms together. And we feel that that's -- the second cohort is necessary in order for us to secure approval. So our plan remains unchanged in terms of submitting both data sets together once this group reaches their one year follow-up.

Larry Biegelsen - *Wells Fargo Securities, LLC - Analyst*

Thanks for taking the question.

Doug Godshall - *HeartWare International Inc - President & CEO*

Thanks, Larry.

Operator

Matthew O'Brien, William Blair.

Matthew O'Brien - *William Blair & Company - Analyst*

Hey, guys. This is Kayla in for Matt. Thanks for taking our questions.

Doug Godshall - *HeartWare International Inc - President & CEO*

Sure.

Matthew O'Brien - *William Blair & Company - Analyst*

So the two year rolling average I guess for international unit growth took a step back in the quarter. So I'm just trying to understand what's going on outside the US, and particularly in Europe, if you're seeing any impact from competitive product trialing? Any commentary there would be helpful.

Doug Godshall - *HeartWare International Inc - President & CEO*

That's funny, Kayla, because I was psyched by our quarter.

Matthew O'Brien - *William Blair & Company - Analyst*

Sorry. I'm sorry we missed it.

Doug Godshall - *HeartWare International Inc - President & CEO*

I'm going to go slit my wrist. I'm depressed. So I don't know.

It's -- frankly, as I look at the past 12 months to 18 months, it's -- the strangeness of international is it's been actually more consistent than it has -- than it had been historically. So the lumpiness that always affects VADs has been a -- is a little less apparent internationally as we've -- I think in part because we've expanded so substantially geographically. Because you've got more folks throwing pennies in the jar every month.

And as we've worked diligently to ensure that we're supporting customers, getting good outcomes, and more countries come on with reimbursement and the like. So I don't have the perception that there's been any real meaningful share loss.

We have sites here and there that every now and then shift a little bit one way or the other. But we feel like we're in a very strong position vis-a-vis the various competitors that have CE Mark and hopefully will continue that way. I don't see a negative trend on --

Peter McAree - *HeartWare International Inc - CFO*

No. Part of the quarter-to-quarter phenomena is we were a bit stronger with distributor sales in Q1 pulling out lumpiness at distributor sales, the direct channel sales were actually quite consistent and strong. And the trend was growing and improving. The -- and the distributor shift was also partly the reason why in our ASPs for the second-quarter, you see that we have more direct channel sales momentum with influencing the overall average selling price a bit.

Matthew O'Brien - *William Blair & Company - Analyst*

Okay. That make sense. And then to follow-up on a prior MVAD question, you mentioned that in Canada it was tough to find a specific patient population. That current generation products could be used -- could not be used as a solution. So what do you think is really going to drive that shift away from earlier generation products, and the use of MVAD longer-term once it is available?

Doug Godshall - *HeartWare International Inc - President & CEO*

Okay. So full disclosure, I'm like -- I'm biased. So as long as you recognize my bias that I joined the Company in 2006 because I saw a prototype of MVAD. And I thought this Company has a huge upside potential, in part because of that product. So I've been waiting for this pump as long as everybody other than Jeff LaRose, who invented it.

So with that bias aside, as I think I can objectively assess the response that I see from physicians when they see that device, it's they can't wait to get it. The volume of the device that sits outside the heart is so small that it just is anatomically I think ideal, or best of current options or better than current options, including the HVAD. If the impeller geometry changed and sheer reduction proves out in the clinic, you're getting a super small size with no trade-off in terms of blood handling characteristics.

And actually, potentially a meaningful upgrade in blood handling characteristics, based on our bench and animal testing. So that also should result in potentially a notable reduction in adverse events, versus current devices. So size and performance should be notably observably better, obviously the performance one will just take time for people to actually confirm.

It's not like when you turn it on, all of a sudden the patients get healthier faster than the other devices. But I think it's more of the downstream adverse events should be lower, as you start to aggregate patient volume.

So it's -- I'm relieved that when we had to describe to our investigators, hey, this is going to take a little bit longer than I thought, they're just 'bring it on as soon as you have it. I can't wait to use this thing.' So their enthusiasm remains high, and for some reason they remain patient with the Company even though we are impatient with ourselves for having this added delay.

Matthew O'Brien - *William Blair & Company - Analyst*

Great. Thanks so much guys.

Doug Godshall - *HeartWare International Inc - President & CEO*

Thank you.

Operator

Bruce Nudell, Credit Suisse.

Bruce Nudell - *Credit Suisse - Analyst*

Good morning. Thanks for taking the question.

Doug, we know there's going to be an impact on MVAD timing. Is there going to be any impact of the warning letters on your ongoing dialogue with the FDA regarding the DT trial? And is there any chance that this could spill over long enough to impact that trial?

Doug Godshall - *HeartWare International Inc - President & CEO*

So I hope not, in terms of length of time. I think unlike larger companies, like the one I used to work for, when we got a corporate warning letter, we had plants all over the world. It affected so many facilities.

We had cobbled together multiple different quality systems from the different acquisitions we had done. And that made it materially more complex to figure out how to work through the warning letter that BSC had back then. Ours is disappointing personally, that I wanted to be a Company that grew fast that didn't get a warning letter.

So now we're trying to continue to grow fast, and do a turnaround at the same time, in terms of our internal systems. But there's a line of sight advantage that you have when you're at our size, versus widespread around the globe. It does not diminish the magnitude or importance to us.

And yet, as I look at the work streams we've identified, the vast majority of our initial work activities will be completed this year. There are others that will go into next year as well. And we'll probably identify additional work as we dig in and mitigate some of the areas that were identified, and others that we have identified through internal audits. And so, even if we completed everything this year, it does not suggest that suddenly the first-quarter of next year the FDA will say, okay that was good work. Now you're all done.

So as we described, it'll take a little bit of time. I don't expect it would take all the way to the time when we would be anticipating filing for DT. I was encouraged by the dialogue regarding thoracotomy, the warning letter it never came up. Granted, it's a different branch of the agency, but they were thoughtful in their review of our proposal to use INTERMACS.

Maybe we misinterpreted them a little bit when they were saying, why don't you use retrospective data to support your filing? And maybe what they were saying was use retrospective data to create as performance goal, versus use retrospective data and just file on INTERMACS. Although, it seemed pretty clear to us initially that they were saying use INTERMACS, and maybe they just thought about it more and realized that that's a little too less burdensome and they wanted a little more burdensome than that.

And we're actually pretty enthusiastic about starting a trial now that we have clarity. So the thoracotomy dialogue didn't feel like an agency that's out to get us and is going to hold the warning letter over our head. Which in no way guarantees that they won't hold it over our head later, but at least at this juncture, we're not sensing it.

Bruce Nudell - *Credit Suisse - Analyst*

Perfect. And just if you could briefly characterize what do you think the volume growth in the US and ex-US markets were this quarter?

Doug Godshall - *HeartWare International Inc - President & CEO*

I'm going to pass on that again, just because I don't have that -- internationally obviously, it's a little bit easier for us. Because of our -- we're not constrained on with a label constraint like we are in the US. The US, is a little hard to project.

So we certainly aren't changing our position as we have moved -- it feels like we have collectively moved well past the angst of the fourth-quarter of last year. The news flashes that folks were afraid were going to really do a downdraft on the market I think are behind us, and it feels like the momentum is good in the market.

Bruce Nudell - *Credit Suisse - Analyst*

Perfect. Thanks so much. Have a great day.

Operator

Steve Lichtman, Oppenheimer.

Steven Lichtman - *Oppenheimer & Co. - Analyst*

Thank you. Good morning.

Doug, just to confirm again on MVAD, between now and through submission in the few months ahead, the work that you guys are doing is running through the same sort of validation -- testing and validation upgrades that you think are required for HVAD. That is just if you can talk a little bit more about specifically what you guys are going to be doing over the next handful of months here on MVAD specifically.

Doug Godshall - *HeartWare International Inc - President & CEO*

Yes. So as I mentioned earlier, we -- the overall theme of the FDA audit and then subsequent communication with us is both make sure you're buttoned up on your documentation, make sure you're buttoned up on your validations. And then in a specific area of validation, make sure you have specifically validated any of the equipment that's used to produce your product or measure your product and the like. And so there's -- that can cover a wide array of things that can be measuring equipment.

It can be what you test your batteries with, et cetera. So, recognizing a need to ensure that when we submit the document to the FDA, that if they have just said make sure all your equipment is validated, we'd better make sure all of our equipment is validated for MVAD. Because it's not the same equipment that we're making HVAD with.

Additionally, as soon as we got the letter, we pulled aside a group including some external experts and said okay, do an audit of all of our documentation and all of our test reports, all of our findings. Make sure that we are really clean in terms of how we've written the test reports, what we've documented, how we've run the tests. Make sure we're compliant with all of the external standards, so that there's no -- we are not giving up any steps.

And so we've been working through that -- we worked through that internal audit process, and did identify some things that we needed to clean up a little bit. And that's the parallel process that's going on right now to ensure that, again, there's no missing pieces. Which, we were in very good shape, but not all the way there.

And again, I think the integrity of the MVAD data is night and day relative to the data we had when we first submitted on HVAD. But times have changed, expectations are higher. And certainly now, in general, with regulators compared to 2007 and 2008, and now expectations on us have just amped up considerably. And so trying to cut corners would be a bad choice at this point.

Steven Lichtman - *Oppenheimer & Co. - Analyst*

Okay. And then just a follow-up, you've talked in the past about an upgrade on the control I think it's the PAL maybe. And I know you had talked about previously launching that with MVAD. Any thought about separating the pathway there, and launching that new controller with HVAD?

Doug Godshall - *HeartWare International Inc - President & CEO*

Yes. So we see -- in fact, I just met with the group that's helping us design and manufacture that system last week. And as I described to them, we see PAL really as the backbone for running all of our pumps in the future. So it may not run CircuLite initially when it goes back in the clinic, but it's such a patient-friendly intuitive, simple, but elegant system that we certainly envision that that's our platform for the next multiple years across our multiple pump platforms.

We can't, however, take an MVAD pump which has one motor and three internal cables in the drive line and a smaller connector, and use that same controller to power HVAD, which has had six internal cables, two motors, and a larger connector. So it's -- at one point, we had contemplated one controller for both pumps. But it would have ended up becoming a much larger controller to accommodate the complexity of running two different kinds of pumps.

We are moving forward with an HVAD version, and are encouraged by what we're seeing. Although, at this point, it looks like it's going to be a slightly different shape just because of the dual motors in HVAD just requires a little bit more space inside the system. So it won't look identical to the MVAD version, which should hit the clinic first. But we're -- it's not lost on us that for the thousands of patients on HVAD, they would all I think benefit from a more elegant system, which is what we believe PAL will be.

Steven Lichtman - *Oppenheimer & Co. - Analyst*

Got it. Thanks, Doug.

Doug Godshall - *HeartWare International Inc - President & CEO*

So -- and I know as I seem to do often, we're running a little bit long. So I'll take two or three more calls, and I'll try to talk less.

Operator

David Roman, Goldman Sachs.

Chris Hammond - *Goldman Sachs - Analyst*

Hello, guys. It's Chris Hammond in for David. Thanks for taking the questions.

I won't belabor on the MVAD issue, but I would like to go back to the ENDURANCE trial. So just doing some back of the envelope math, it looks to me, you said that you guys have done 36 implants in the quarter, 35 last quarter, and then let's call it mid-teens in the fourth quarter. Which just on the back of the envelope, tells me a couple of things.

Is, one, it seems that on a two-to-one control matching that HVAD is not really enrolling as fast as HeartMate is. And secondly, with only we'll call it 150 total enrolled to date, it doesn't seem to me that the early first quarter of 2015, completing the enrollment is actually a realistic goal.

So, I was hoping you could update me on or update us on what's your latest thinking on when you can complete that trial all in? Because just doing the math now, I feel like mid-2015 to late 2015 is a more realistic option.

Doug Godshall - *HeartWare International Inc - President & CEO*

So it's not physically possible for one -- well first of all it's a two-to-one randomization, and we're right on track with the two-to-one randomization. And one arm doesn't enroll differently than the other arm. The patient shows up, and then they find out which device they're going to get through an automation randomization scheme.

So it -- your numbers are probably not all that wrong. So, sort of nine units in the fourth-quarter of last year. And so in total, we're at about 100-ish HVAD implants to date in the trial.

If we continue to track at the 30 plus per month total randomized range, I think that pulls it in considerably, relative to your timeline. So we did see a pickup in the first-quarter that then fell off a little bit in April, May. We don't know why, and then it has reaccelerated June, July.

I think we've helped stimulate that through our efforts partly, and I think partly it's also just recovery from a little bit of a lull. And certainly, we're pushing aggressively to try to move back up towards the peak enrollment in the high 30s that we had anticipated we would be peaking at per month. Similar to what we had seen in the original trial when we were peaking in that trial. So I think in part, as we were working through organizational transitions and the like, we may have lost a little bit of attention and focus on our end that is renewed now and contributing.

Operator

Suraj Kalia, Northland Securities.

Suraj Kalia - *Northland Securities, Inc. - Analyst*

Good morning, gentlemen. Thank you for taking my questions.

Doug, forgive me for going back to the MVAD. On a more fundamental level, I'm curious how the HQ curves of the MVAD look versus the HVAD. Because our understanding for the field is that the RPMs are almost seven times better than HVAD, and I wanted to juxtapose that with your earlier comments of the kind of patients not covering [inaudible]. Is it that the MVAD is most suited towards class III?

Or are they sticking with the class IV? Because the output at the RPMs, at least in that current literature, it's interesting to compare to HeartMate and HVAD. And I'm just curious to get your thoughts on that. Thank you for taking my question.

Doug Godshall - *HeartWare International Inc - President & CEO*

Sure. So as I know you are well aware, Suraj, rotational speed is not really the critical metric for assessing a pump's performance. Because it's a -- the output of a pump is going to be a function of rotational speed and diameter of the impeller or tip speed. And so while we will be in the probably 15,000 to 18,000 RPM range with MVAD to get us to the 5, 6, 7 liters of flow, which is where 90% plus of our patients are, we'd be I think about 1% of our patients with HVAD get 8 liters of flow, and that's probably not even 8 liters of flow it's probably just a reading error.

So the MVAD is absolutely in the sweet spot of the class IV patient demand based on our data and based on our best interpretation of the HeartMate II data, which is a little harder to get flows from. But as we take their speeds and overlay it against the various Q curve that's published, they're probably in about the same range, 4 to 6 liters, we're generally in the 4 to liter range with HVAD.

The HQ curve for MVAD is going to be a little bit steeper, since it's an axial flow pump. And that will increase pressure through the pump, which is one of the reasons why we'll have a -- but it also enables us to implement pulsatility very easily. We'll have all sorts of suction response algorithms, it's going to be a very sophisticated system, much more biologically responsive than the HVAD.

The patients that are in Canada ... for the Canadian government that you're referring to, to get special access you have to prove that there's a patient who other devices cannot serve. And we and the clinicians who were submitting, just weren't able to prove that the HVAD couldn't treat everybody.

And the fact that we've done so many pediatric cases in Canada, it's awfully hard if you're treating five and six-year-olds, it's hard to convince the Canadian government that this small device can somehow treat somebody that the HVAD can't. And so you sort of lose the argument, in part, because of how well the HVAD is working. Next question. Is there one?

Operator

Danielle Antalffy, Leerink Partners.

Danielle Antalffy - *Leerink Partners - Analyst*

Hello. Good morning, guys. Thanks so much for squeezing me in.

Doug, just wanted to talk about the US market a little bit. So last quarter, it looked like a pretty significant market share shift towards you guys in bridge to transplant. And I think part of that, at least from your competitor's perspective, was driven by the New England Journal of Medicine article on increasing rates of thrombus with the competitive device.

Just wondering if number one, you agree with that assessment? Are you seeing in centers where you're currently -- that currently have the HVAD, are you seeing them shift market share in part because of that? And if so, has that trend continued into the second quarter, and how sustainable I guess do you think that trend might be and the benefit there?

Doug Godshall - *HeartWare International Inc - President & CEO*

So if you think about our historical experience internationally, we've been very fortunate that on balance, we don't go back. We have not gone backwards often at any sites in terms of share, and rarely do we -- if we do see a shift away from us, it doesn't tend to last very long. And so, we've been really flattered and blessed that that has been the case internationally.

And our hope was always if we get -- if we can migrate our experience internationally to the US, serve our customers well, help them get good outcomes, as we've seen internationally, that we would enjoy the same traction in US centers. Such that, once you get comfortable with our device, you expand utilization of our device versus remaining static or declining. And the -- none of that would be true if our competitor's device was perfect, and likewise, if our device was perfect we wouldn't need to work so hard.

And so both devices have their -- have challenges. Not every patient unfortunately survives and gets a perfect outcome, and our goal is to get as close to that as we can. But for whatever the reason that a site initially decides to try our device, our goal is, of course, to make sure that everything goes incredibly well. So that they decide that their next patient should also get an HVAD.

So to the extent that the New England Journal might have stimulated a few sites to think about trying our device or using it a little bit more, that only has a durable effect if the patients do well. If the patients don't do well, they will say, well, the New England Journal might have been a good reason to try it, but it's not a good reason to keep going.

And so we're -- it doesn't come up anymore. Nobody says, oh by the way, I just noticed in my waiting room in a New England Journal on bad thrombus. Therefore, I'm going to start using your device. So I think it's had its effect, and now it's much more what is my experience with one device?

Am I satisfied or dissatisfied? And would I be potentially more satisfied if I tried the HVAD?

So with that, I think -- I don't know if we have any other questions. I don't think -- thankfully, Danielle, you snuck in at the end. I thought you had forgotten about us, so thank you for joining and, thanks all for joining our call today.

We're quite optimistic about the future. I think the next few months are going to be painful in some ways, and incredibly rewarding in many other ways. So hopefully in the future, I won't be having to talk about delays and submissions and the like, we'll be able to talk about trials starting and more predictable more rigorous development timelines.

So with that, thanks for your call. I look forward to seeing you folks, and have a good Summer.

Operator

Thank you. Ladies and gentlemen, this does conclude today's teleconference. We thank you for your participation, and you may disconnect your lines at this time.